

Remarks

Claim amendments

Claims 1-7 are under examination in the present application.

The formal phrase "What is claimed is" has been added as an opening phrase for the claims. Further, the claims have been amended to accord with the U.S. practice and recite "A process" in the case of the independent claim, and "The process" in the case of dependent claims. Dependent claim 3 is cancelled and its contents incorporated into the independent claim 1. Claim 4 is amended to recite "the caps of the other lysis vessels." The amendment is supported by the specification, *see e.g.* p. 9, lines 9-10, and p. 19, lines 19-20.

Claim rejections under 35 U.S.C. §112

Claim 5 was rejected under 35 U.S.C. §112, second paragraph for being indefinite. The examiner suggested that the limitation "*the caps of the matrix unit are in the leaned-to position*" should read "*matrix vessels and caps of the matrix unit are in the leaned-to position.*" There appears to be some confusion about the caps and the vessels. On page 9, lines 3-10 the Applicants describe the three positions of the *caps* of the lysis unit, the matrix unit and the closure unit. These cap positions are open, closed, and a "position in which the cap is lowered and rests on the opening of the vessel below" (*see* p. 9, lines 9-10). As is clear from the specification, the term "leaned-to" refers to the latter position of the caps. Further, the advantages of the "lean-to" intermediate position of the cap are described as "The cap can be opened again without the large exertion of force from the position in which the cap rests on then opening of the closure [...]." *See* p.15, lines 19-20. Nothing in the disclosure states or suggests that the vessels may also be leaning. As is shown, for example, on Figure 4a, a matrix vessel (21) fits into a matrix unit (20). When placed in the unit (20), the vessel (21) does not have the freedom to assume a lean-to position as suggested by the examiner. Therefore the existing claim limitation that the caps are in the leaned-to position adequately describes the applicant's invention as disclosed.

In view of the foregoing explanation, the examiner is respectfully requested to withdraw the rejection under 35 U.S.C. §112 (second paragraph).

Claim rejections under 35 U.S.C. §102(b)

*a. Rejections over Uematsu*

Claims 1-3 and 6-7 were rejected over U.S. Patent No. 5,538,849 to Uematsu. The rejection is respectfully traversed. The examiner stated that Uematsu " teaches a process for

isolating a purified biological material.” The examiner continued that Uematsu teaches each of the steps a) through g) of the Applicants’ claim 1. In fact, Uematsu teaches not a process for isolating any material, but a process for detecting nucleic acids by hybridization. As such, the Uematsu process is lacking several steps taught by the Applicants’ method. For example, Uematsu does not teach step b (adding lysis liquids), step c (transferring liquids in a matrix unit containing a matrix), step f (filling the matrix vessels with elution fluid) and step g (extracting the elution fluid). Uematsu does not use lysis reagents because no entity to be lysed (such as a cell) is present in the sample. Instead, an alkaline denaturant is used to merely separate the strands of already isolated nucleic acid (see Uematsu, col. 5, lines 40-44). The alkaline denaturant alone will not act as a lysis reagent, i.e. will not lyse cells. A typical lysis reagent must contain a detergent, such as for example, SDS (see Please cite as: CSH Protocols; 2006; doi:10.1101/pdb.prot3906, “Preparation of Plasmid DNA by Lysis with SDS”).

Further, Uematsu does not use a matrix to bind the sample during the nucleic acid hybridization. Instead, the sample solution is placed into a vessel where the probe is bound to the internal surface of the vessel, not to the matrix. See Uematsu, col. 5, lines 44-46. Finally, Uematsu does not elute the sample with the elution fluid after the nucleic acid hybridization has been detected by measuring light emission. The detection appears to be the end-point of the Uematsu method. It is apparent that multiple limitations of the Applicants’ claim 1 are missing from the Uematsu reference. Therefore the claim is not anticipated.

Claims 2, 3, 6 and 7 depend ultimately upon claim 1 and thus incorporate every limitation of that claim and are likewise, not anticipated by Uematsu. Withdrawal of all rejections over Uematsu is respectfully requested.

*b. Rejections over Fujishiro*

Claims 1 and 6-7 were rejected over U.S. Patent No. 5,645,723 to Fujishiro. The rejection is respectfully traversed. As amended, claim 1 requires that the elution vessels be closed with the closure unit in step h) after the biological material is collected in step g). Fijishiro does not teach that the elution vessels be closed with the closure unit. Fijishiro does not teach a closure unit. Every type of the sample vessel in Fujishiro remains open. See col. 8, lines 43-47. Therefore Fijishiro does not anticipate the amended claim 1. Claims 6 and 7 depend upon claim 1 and incorporate all the limitations of that claim. Therefore these claims are also not anticipated by Fujishiro.

In view of the foregoing, withdrawal of all rejections over Fujishiro is respectfully requested.

*c. Rejections over Bienhaus*

Claims 1 and 6-7 were rejected over a WIPO publication WO 96/31781 by Bienhaus. As amended, claim 1 now requires "closing the collecting unit with a closure unit". Bienhaus does not teach a separate closure unit. Instead, each tube (vessel) in Bienhaus has an individual cap, physically unconnected to either the vessel or the unit. Each cap in Bienhaus must be individually opened and closed. Because at least one limitation of amended claim 1 is not disclosed or suggested by Bienhaus, the §102 rejection of the claim may no longer be sustained. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 6 and 7 depend upon claim 1 and therefore incorporate all the limitations of that claim. Withdrawal of the rejection of the dependent claims over Bienhaus is also respectfully requested.

#### Claim rejections under 35 U.S.C. §103

##### *a. Rejections over Acuff*

Claims 1 and 2 were rejected over U.S. Patent No. 4,142,858 to Acuff, a single reference. The rejection is respectfully traversed. The examiner stated that Acuff, like Uematsu, "teaches a process for isolating a purified biological material." The examiner continued that Acuff teaches each of the steps a) through g) of the Applicants' claim 1. In fact, the Acuff process is clearly lacking at least one step, step e) of the Applicants' method. Step e) requires "placing the matrix unit on a collecting unit with collecting vessels which are arranged such that *at least the outlet openings of the matrix vessels extend into the collecting vessels*" (emphasis added). As is clearly shown on Figure 1 of Acuff, and expressly stated in the text (Acuff, col. 6, lines 51-54), the outlet openings do not extend into the vessels. The examiner stated that the plurality of vessels would be a mere duplication of a single vessel of Acuff and thus unpatentable. It is possible, as the examiner suggests, that a desire to multiplex the Acuff method could be a motivation for a person of ordinary skill. However, the examiner has not established what if anything would motivate a person of ordinary skill to add step e) missing in Acuff.

The foregoing indicates that the *prima facie* case of obviousness over Acuff has not been established. Therefore claim 1 may not be rejected as obvious over Acuff. Claim 2 depends upon claim 1 and incorporates all the limitations of that claim. Therefore rejection of claim 2 likewise, may not be sustained. Reconsideration and withdrawal of all obviousness rejections over Acuff is respectfully requested.

##### *b. Rejections over Uematsu in view of Mochida*

Claims 4 and 5 were rejected as obvious over Uematsu in view of the U.S. Patent No. 4,479,720 to Mochida. The rejection is respectfully traversed.

As discussed above, Uematsu lacks several limitations of the Applicants' invention, namely, step b (adding lysis liquids), step c (transferring liquids in a matrix unit containing a matrix), step f (filling the matrix vessels with elution fluid) and step g (extracting the elution fluid). Mochida teaches an apparatus for rotating reaction vessels while the vessels are in the leaned position. Thus Mochida does not supply the elements missing from the Uematsu reference. The examiner has not shown how Uematsu, Mochida or their combination either teach or suggests the invention (steps a-g) as described in claim 1, upon which claims 4 and 5 depend. Therefore the *prima facie* case of obviousness has not been established.

With respect to the leaned-to position in particular, the rejection is moot in view of the resolution of the misunderstanding discussed in relation to the "lean-to" term in claim 5. As explained in relation to the 35 U.S.C. § 112 rejection of claim 5, the claim indeed refers to leaned caps, not leaned vessels. The examiners suggestion that the vessels, not the caps are leaning is not supported by the specification. While Mochida may imply that the vessels may be leaned inside the device, Mochida does not teach any vessel caps or the position of vessel caps.

In view of the foregoing the rejection over a combination of Uematsu and Mochida may not be sustained. Reconsideration and withdrawal of the rejection are respectfully requested.


Conclusion:

In view of the above, Applicants believe all claims now pending in this Application are in condition for allowance. It is believed that no fees are due at this time, however, the Commissioner is authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0812.

If the Examiner believes that a telephone conference would expedite prosecution of this application, the examiner is invited to call the undersigned directly at 925-730-8567.

Respectfully submitted,

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